Panelist Questions for ChemCon TSCA Seminar

TSCA Section 6 Issues (The last session on the workshop agenda is a Q&A on Section 6 risk evaluation, so most of these questions relation to Section 6. Other questions are noted on other TSCA provisions)

Tala: Please elaborate on the lessons learned by EPA from the reactions of the SACC and the public to the risk evaluation process thus far? Might anything change in the future, and if so, what might that involve? Can you tell us more about the SACC feedback on PV 29, for example?

What are the thoughts of **other panelists** regarding lessons learned and possible future changes?

EPA applied a Systematic Review approach in conducting the first round of Risk Evaluations. The SACC identified a number of general and specific issues regarding EPA's approach. What was your reaction to EPA's Systematic Review approach? What did you like about EPA's approach, and what could be strengthened going forward?

Tala: Anything to add?

Tala: To keep producing 1,000-plus page documents burdens EPA risk assessors, and it is not necessarily helping the public or SACC review processes. How likely is it that EPA will update some aspects of its Risk Evaluation guidance materials, the Risk Evaluation procedural rule, or other Risk Evaluation documents, such as systematic review, given the experience learned to this point? Where do you think changes are most likely?

What do other panelists think? Is this level of detail necessary?

ALL: The draft Risk Evaluations released to date include EPA's provisional determination of unreasonable risk, an aspect that has received significant attention from the SACC, the public, and the trade press. The Risk Evaluation procedural rule, however, states that EPA is not seeking peer review of this component of the evaluation.

From my perspective, the unreasonable risk determination is an EPA call that combines science, policy, law, and regulatory policy. Thus, it is not a scientific judgment *per se* and for this reason does not fit within the scope of the peer review request to SACC. Given this situation I question, why not wait to release the unreasonable risk determination until the Risk Evaluation is prepared in final, including addressing peer review issues, and then include EPA's risk determination in the final publication? I note that, as EPA states in its guidance, the risk determination is not subject to peer review, so no harm is done in using this approach. A possible benefit is that it would allow EPA to show that the public comments and the peer review recommendations and/or comments were considered in the final drafting.

What is the reaction of the panelists to this suggested approach -- do you see any issues or problems? Alternatively, do you see possible benefits? Please explain your thinking.

EPA has received requests from industry that EPA conduct risk evaluations. These involve two PBT chemicals and two phthalates. New TSCA also allows "interested persons" to conduct and submit risk evaluations to EPA that, according to TSCA Section 26(l)(5), "shall be considered" by EPA. Are you aware of any planned or ongoing efforts by industry or others to prepare Risk Evaluations?

While EPA has recently indicated that it intended to use Section 4 testing authorities to fill data needs regarding PV 29, it did not otherwise use testing to anticipate and fill data needs prior to developing the first set of risk evaluations, perhaps because of time constraints. The adequacy of the data set for several of the Risk Evaluation chemicals (*e.g.*, PV29, 1,4-dioxane regarding exposure) was nonetheless questioned by the SACC.

Might this, perhaps more pointedly, should this issue be considered early in the coming round of high-priority Risk Evaluations? How might this be done as part of EPA's approach, or is it best considered an issue? Could this be worked into the risk evaluation scoping step, where it could be useful and timely for shorter term testing?

The same question regarding prioritization, what are your thoughts about EPA taking early steps this year or next to develop test data that might be helpful in informing the next round of prioritizations, perhaps focusing on the Work Plan and SCIL chemical lists? These have been the sources of the prioritization candidates thus far. If you think this would be a useful step for EPA to take, are there any suggested testing strategies that you might have EPA consider to better inform prioritization? Might SIDS or its equivalent be identified as a base set?

EPA has met its obligation and is not required to perform any additional low-priority designations. Does EPA plan to designate additional low-priority chemicals in the next year or two? If so, is EPA open to requests for low-priority nominations?

Section 5 Issues

EPA's *Working Approach to Making New Chemical Determinations under TSCA*, to my mind, is greatly improved, detailed, and helpful. Not everyone agrees, of course, but for those of us who work with chemical innovators, the document is useful. What is OPPT's next step here?

What, **Tala,** do you say to detractors who believe issuance of non-5(e) order SNURs is impermissible?

What percentage of new chemical determinations are "not likely" without a SNUR?

Fee Rule

There is much discussion and apparent anxiety over the fee rule and what entities are "in" and "out." Ryan, you spoke a week ago today and last Friday helping to explain the fee rule and the "next 20" high-priority chemical substances. I want to ask other panelists whether EPA should define the boundaries on a chemical-by-chemical basis or cast the fee net as broadly as possible. Can you give examples of when EPA should apply the article exemption to fees or when EPA should define a threshold for the applicability of the fee?

Section 4 Issues

Is there any Section 4 testing planned in OPPT's future?

Section 8 Issues

Can EPA comment on the effort that it expects will be required to review CBI claims?

Agency Resource Issues

How is the hiring process going?

What areas in particular are most in need of support?

With OPP moving to D.C. later this year, might there be greater opportunities for collaboration on risk assessment and evaluation issues?